Canadian Blood Services
BLOOD PLASMA STEM CELLS ORGANS & TISSUES

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Ms. Shelly Chen
Regional Regulatory Compliance and Enforcement Officer - GMP Inspection Central
Regulatory Operations and Enforcement Branch (ROEB)
Regulatory Operations and Regions Branch
Health Canada
2301 Midland Avenue
Toronto, ON M1P 4R7

Dear Ms. Chen:

Re: Further to the Responses to the Health Canada Inspection of Wholesale Activities at Brampton Operations 2019-10-23 to 2019-10-25

The following are the actions taken by Canadian Blood Services in response to the Health Canada letter dated 2020-01-10, requesting additional information for observations to the Exit Notice for Health Canada's Inspection of wholesale activities at Brampton Operations.

C.02.015 - Quality control department

1. **Deficiencies were noted regarding temperature mapping and monitoring of the storage areas for DIN products. For example:**
Temperature in the walk-in fridge RFG 2000 was not monitored at the worst case location identified in the loaded temperature re-mapping study (protocol #2017-03-24-115938) conducted in response to the installation of new storage shelves. There was no written rational available to justify the placement of the current temperature monitors.

To re-qualify walk-in refrigerator RFG 2000, a loaded chamber mapping was completed with protocol IOQ-WRF-001-2017-03-24-115938 version 7.0. The data demonstrated that the system was able to maintain the required operating temperature throughout the chamber with additional racking and potential payloads. As the results of the loaded chamber mapping were successful (all temperatures remained within specifications), there is no concern with the overall validated state of the system, including the location of the monitoring probes that were determined in the initial qualification.

For the following reasons we consider empty chamber temperature mapping to represent the worst-case scenario to determine the location of warm and cold spots of a refrigeration systems: (1) a walk-in refrigeration system is specified for use as a storage unit to maintain temperature, (2) there is limited thermal mass within the chamber to contribute to temperature stabilization, and (3) during empty chamber mapping, temperature sensors are exposed to air and are, therefore, most responsive to temperature fluctuations. Whereas the loaded chamber mapping is performed to verify that the unit is operating within specifications.

The empty chamber temperature mapping of walk-in RFG 2000 was completed in the initial qualification in 2016, covering the entire usable space within the system. A note-to-file will be added to the protocol clarifying the decision in maintaining the monitoring probes at the current locations. This will be completed by 2019-12-31.

In addition, protocol IOQ-WRF-001 will be revised by 2020-03-31 with the following:

a. Requirements to identify the final monitoring probe placement and a documented rationale for the selection of the worst-case locations following empty chamber mapping.

b. A requirement for the review of loaded mapping data to demonstrate the system's capability in maintaining required temperature, and the re-assessment of the locations of the monitoring probes when acceptable performance of the system cannot be demonstrated.

Health Canada Follow-up letter dated 2020-01-10:

Regarding your corrective action of revising mapping protocol, does it include protocol for other onsite storage units such as the walk-in freezer?

Canadian Blood Services Response:

Revisions to protocol IOQ-WRF-001 will apply to both the walk-in freezers and refrigerators.

If you require clarification or further information, please do not hesitate to contact the undersigned. **Please refer to the above control number in all correspondence.**

Sincerely,

Dr. Christian Choquet
Vice-President
Quality & Regulatory Affair
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cc: Melanie Bhangoo
Manager GMP Inspection
GMP Inspection, Central